

ANNEX

(a) Applicant and Authorisation holder:

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, B-1040 Brussels - Belgium

On behalf of Pioneer Hi-Bred International, Inc. - 7100 NW 62nd Avenue – P.O. Box 1014 – Johnston, IA 50131-1014 - United States of America.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (2) feed containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (3) DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean, as described in the application, has a reduced expression of the soybean enzyme omega-6 desaturase, which results in a high oleic acid and reduced linoleic acid profile, expresses an optimized *Glycine max-hra* gene, which confers tolerance to acetolactate synthase-inhibiting herbicides and expresses the CP4 EPSPS protein which confers tolerance to glyphosate herbicides.

(c) Labelling:

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';
- (2) For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products;
- (3) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean with the exception of products referred to in point (a) of Article 2.

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based methods for DP-3Ø5423-1 and MON-Ø4Ø32-6 soybeans; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;

- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
 - (3) Reference Material: ERM-BF426 (for DP-3Ø5423-1) and ERM-BF410 (for MON-Ø4Ø32-6) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>.
- (e) **Unique identifier:**
DP-3Ø5423-1 × MON-Ø4Ø32-6
- (f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**
[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].
- (g) **Conditions or restrictions on the placing on the market, use or handling of the products:**
Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003
- (1) The authorisation holder shall collect the following information:
 - (i) Quantities of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean oil and DP-3Ø5423-1 × MON-Ø4Ø32-6 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food.
 - (ii) In case of import of products mentioned under (i), results of database searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.
 - (2) The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.
- (h) **Monitoring plan for environmental effects:**
Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
[Link: *plan published in the Community register of genetically modified food and feed*]

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.